

Instructions for Use

Viamed Medical Oxygen Sensors

Warnings and Precautions

- It is the responsibility of the user to determine the suitability for use of the sensor.
- Follow the instructions for use of the oxygen analyzer and for the replacement of the oxygen sensor/s.
- To avoid cross-infection, please strictly follow the instructions for use from the oxygen analyzer manufacturer.
- Refer to the oxygen analyzer instructions for use to determine any required preoperative checks.
- Sensor contains, encapsulated by a housing: lead (Pb), lead oxide (PbO); and concentrated potassium hydroxide solution (KOH) (between 2 and 5 mol/L). Lead and lead oxide are toxic and dangerous to the environment. Concentrated potassium hydroxide is corrosive (see safety data sheet). Do not open the housing or penetrate the permeable membrane. Do not touch a damaged sensor without protective gloves. In the case of leakage, avoid contact with eyes.
- The sensor is not suited for use in a magnetic resonance imaging (MRI) environment.

Indications for Use

Viamed medical oxygen sensors are intended as the oxygen-sensing component of an oxygen analyzer that measures oxygen concentration in breathing gas mixtures in the following applications:

- Sensing device for oxygen in the control device of oxygen concentrators
- Sensing device for oxygen in medical ventilators
- Sensing device for oxygen in anaesthesia equipment
- Sensing device for oxygen in incubators
- Sensing device for oxygen in oxygen hoods & tents

The use is limited to system monitoring. The sensors are not suited for breath-by-breath analysis of breath gases.

If the sensor is intended to replace the original oxygen-sensing component of an oxygen analyzer, consult the Viamed cross reference list at <http://www.viamed.co.uk/xref> in order to select the appropriate sensor. Do not use sensor/device combinations that are not specified in the cross-reference list, nor in the instructions for use of the device. The use of the sensor is restricted to professional users.

Instructions

The sensor should be replaced only by a professional user. Before insertion into the device, check the sensor for mechanical damage and for humidity or crystallization of salts on the housing. Do not use a damaged sensor or a sensor with crystallization of salts outside. Follow the instructions for use of the oxygen analyzer for the replacement of the sensor. Verify that the sensor can be properly attached to the mechanical and electrical connections of the oxygen analyzer. Calibrate the analyzer in accordance with the analyzer's instructions for use and verify proper gas readings. Oxygen analyzer readings in room air will typically be between 19% and 23% when calibrated in 100% oxygen or another calibration gas level required in accordance with the analyzer's instructions. The sensor should be calibrated at regular intervals (see instructions for use of the analyzer). If calibration problems or unstable signals occur, the sensor must be replaced.

Technical Sensor Specifications

The sensor meets the requirements of ISO 80601-2-55. For detailed technical specifications, please refer to sensor's technical specification sheets, which are available upon request: info@viamed.co.uk

Environmental Specification

Operating temperature:	0 °C ... 50 °C (no fast temperature changes, 30 minutes equilibrium time after fast temperature change)
Operating humidity:	0 %... 99 % RH non-condensing
Storage temperature:	-20°C ... +50°C
Recommended storage:	+5°C ... +15°C
Pressure range:	600 hPa ... 2000 hPa
Warm-up time:	< 30 minutes, after the replacement of the sensor
Influence from anaesthetic agents	Meets ISO 80601-2-55 requirements

Principles of Operation

Viamed medical oxygen sensors are based on the principle of electro-galvanic sensors. They are constructed in a plastic housing containing two electrodes: a precious metal cathode and a lead anode immersed in a liquid electrolyte medium. Electrically the device resembles a very low voltage battery cell. A gas-permeable diffusion membrane provides the interface to the gas sample. The oxygen gas is reduced on the sensing electrode (cathode) and lead is oxidized on the second electrode (anode). The resulting current produces on the load resistor an external electrical voltage signal that is proportional to the conversion of the oxygen. The sensor signal is temperature-dependent and most sensor types are temperature-compensated with an internal temperature-compensating resistor network.

Cleaning / Disinfection

The sensor membrane and the printed circuit board should not come in contact with disinfectant or cleaning agent. The other parts of the sensor can be disinfected by the use of disinfectant wipes or with a surface disinfection agent. Follow the instructions of the producer of the disinfection material.

Disposal

Medical Oxygen Sensors contain lead (Pb) and concentrated potassium hydroxide solution (KOH). Sensors should be disposed of in accordance with local regulations. Further details concerning Environmental and Recycling Information are available upon request: info@viamed.co.uk

Packaging and Labelling Symbols

Symbol	Description
TYPE	Sensor type
PN	Product number
SN	Serial number
	Observe instructions for use
	Date of manufacture
	Manufacturer
	CE-Symbol notified body number
	<p>In accordance with Directive 2002/96/EC (WEEE), the manufacturer will accept the return of the electrical and electronic device for proper disposal.</p> <p>Please note: Medical oxygen sensors contain lead (Pb) and should be disposed of in accordance with local regulations.</p>
	Corrosive
	Storage conditions